

Letter - Seraclone Blood Grouping Reagent Anti-S (Monoclonal)

Our STNs: 125212/0 and 125214/0

Biotest AG
Attention: Mr. William Weiss
Biotest Diagnostics Corporation
400 Commons Way Suite F
Rockaway, New Jersey 07866

Dear Mr. Weiss:

We have completed the review of your amendments dated March 5, 2008 to your biologics license applications (BLA) for the licensure of Blood Grouping Reagent, Anti-Fy^a (Monoclonal) and Blood Grouping Reagent Anti-s (Monoclonal) submitted under section 351 of the Public Health Service Act.

The Traditional 510(k)s submitted on March 22, 2008 (BK080013 for the ancillary reagents to be used for traditional tube testing and BK080012 for use of these and additional reagents on the Tango Optimo) have not received substantially equivalent determinations to date. We cannot approve these applications until the 510(k)s are cleared and all other related BLA submissions, including those from the source material manufacturers, are approved.

We have identified the following issues with your responses:

Labeling

1. Please submit corrected labels to include your full name (Biotest Medical Diagnostics GmbH) and new license number on the vial, container and package insert labels.
2. Seraclone Anti-Fy^a Package Insert
 - a. Under "Summary," it states "Seraclone Anti-Fy^a may cause hemolytic disease..." Please delete "Seraclone."
 - b. Under "Reagent"

- i. It states, "It is derived from red blood cell culture..." Please delete "red blood cell".
 - ii. With respect to Diagast, please delete "FFMU" and insert their current license number.
 - c. Material required but not provided Section. You state that use of an optical aid for reading and grading agglutination results is not allowed. You also reference the Technical Manual, 15th edition in your package insert bibliography. The standard of practice in the US as recommended by the American Association of Blood Banks Technical Manual requires the use of an agglutination viewer to aid in the grading of hemagglutination reactions. This standard operating procedure is accepted for use by CBER as referenced by 21 CFR 606.100(d)(1). If an optical aid cannot be used to grade reactions, please add this contraindication (prominently bolded) to this section to alert the user.
 - d. Summary Section. Please use capital letters for the biologics product proper name, i.e., Blood Grouping Reagents.
3. Seraclone Anti- s (Monoclonal) Package Insert
- a. Please make the same corrections as described in b, c, and d above.

We reserve final comment on the proposed labeling until the applications are otherwise acceptable. We may have comments when we see the proposed final labeling.

Should additional information relating to the safety and effectiveness of these biological IVD products become available prior to our receipt of the final printed labeling, revision of that labeling may be required.

You may request a meeting or teleconference with us to discuss the steps necessary for approval. For PDUFA products please submit your meeting request as described in the FDA Guidance for Industry: Formal Meetings With Sponsors and Applicants for PDUFA Products February, 2000 (<http://www.fda.gov/cber/gdlns/mtpdufa.pdf>). For Non PDUFA products, please contact the regulatory project manager. For details, please also follow the instructions described in CBER's SOPP 8101.1: Scheduling and Conduct of Regulatory Review Meetings with Sponsors and Applicants, available at (<http://www.fda.gov/cber/regsopp/81011.htm>).

Within 10 days after the date of this letter, you should take one of the following actions:

1. amend the applications;
2. notify us of your intent to file amendments; or
3. withdraw the applications.

We stopped the review clock with the issuance of this letter. We will reset and start the review clock only when we receive your complete response.

If you have any questions, please contact the Consumer Safety Officer, Teresita Mercado, at (301) 827-6139.

Sincerely yours,

Elizabeth Callaghan
Acting Director
Division of Blood Applications
Office of Blood
Research and Review
Center for Biologics Evaluation and Research